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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,309	04/20/2004	Michael B. Zemel	31894-199326	2567
26694 7590 02/07/2007 VENABLE LLP P.O. BOX 34385 WASHINGTON, DC 20043-9998			EXAMINER LASTRA, DANIEL	
			ART UNIT 3622	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE			MAIL DATE	DELIVERY MODE
3 MONTHS			02/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/827,309

Applicant(s)

ZEMEL ET AL.

Examiner

DANIEL LASTRA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-24 and 26-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-24 and 26-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/13/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-3, 5-24 and 26-30 have been examined. Application 10/827,309 (METHODS OF PROMOTING CALCIUM CONSUMPTION FOR WEIGHT LOSS) has a filing date 04/20/2004 and is a division of 10066057 01/31/2002 is a division of 09654357 09/01/2000.

Response to Amendment

2. In response to the Advisory Action filed 11/02/2006, the Applicant filed an RCE on 11/13/2006, which amended claims 1, 9, 22-24 and cancel claim 31.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-7, 9-20, 22-24 and 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howard (US 4,237,118) in view of The Milk Mustache Campaign (<http://agcommcase.ifas.ufl.edu/mustache.html>).

As per claim 1, Howard teaches:

A method comprising communicating to a potential consumer *suffering from obesity* that *in combination*:

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a) consuming dietary calcium *in an amount that is above suboptimal, over a period of time from a calcium-containing product (see col 5, lines 1-5), and*

b) *maintaining a restricted caloric diet below ad lib in a range that is about 200 kcal to about 2500 kcal per day, during that period of time (see col 3, lines 35-45),*

has a beneficial effect on body weight or body fat from the consumption of the dietary calcium from the calcium-containing product, the effect selected from the group consisting of inducing weight loss, reducing weight gain, and/or increasing the metabolic consumption of adipose tissue in the individual (see col 2, lines 15-60)

Howard fails to teach:

the communicating being by an entity having a commercial interest in the consumption of the product and wherein the communicating is by a method selected from the group consisting of verbal communication, pamphlet distribution, print media, audio tapes, magnetic media, digital media, audiovisual media, billboards, advertising, newspapers, magazines, direct mailings, radio, television, electronic mail, electronic media, banner ads, fiber optics, and information on a product package, insert or label or directly accompanying the product. However, The "Milk Mustache Campaign" teaches distributing information to potential consumer about milk and its benefits where said information is distributed via print advertisements (see paragraph 1-5). The "Milk Mustache Campaign" does not teach distributing information via electronic media, banner ads, and other methods of delivering promotions. However, Official Notice is taken that it is old and well known in the business art to advertise products using different communications method, such as verbal, e-mails, etc. It would have been

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obvious to a person of ordinary skill in the art at the time the application was made, to know that manufacturers and retailers of calcium-fortified products would use all the available and affordable means to advertise to consumers the benefit of said products, so said consumers are aware of said benefits and purchase said products. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the application was made, to know that any entity having a financial interest in the sale of dairy products or dietary supplements would be motivated to distribute information to potential consumers about milk and its benefits to health, as taught by The "Milk Mustache Campaign" in order to promote the consumption of dairy products by claiming that the consumption of said products would have a benefit against osteoporosis (see The Milk Mustache paragraph 1) and obesity, as taught by Howard. Retailers of calcium-fortified products would be motivated to advertise the benefits of said products in combating diseases and/or maladies, such as osteoporosis and/or obesity, as said advertise benefits would bring more business to said retailers.

As per claim 22, Howard teaches:

A method for inducing the consumption of dairy products by a commercial entity having a financial interest in the sale of the products, wherein the entity distributes information to potential consumers of the dairy products describing weight-control benefits of dairy products attributable to the *combination of*:

a) the consumption of *at least about 57 servings or dairy per month* (see col 4, lines 57-65; "123g/day dried skimmed milk"). Official Notice is taken that it is old and well known that 3 tablespoons of instant dry milk added to 8 oz of water make 1 cup of

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milk (*i.e.* 1 serving) and 3 tablespoons of dry milk is equivalent to 42.45 grams. Howard recommends between 61.3g/day to 123g/day of dried skimmed milk for weight reduction, which is equivalent to 1-3 servings of milk a day, which can be construed as drinking at least 57 servings at month if said person drinks an average of 2 servings per day and does not consume more than the recommended kcal per day.

b) maintaining a restricted caloric diet below ad lib in a range of about 200 kcal to about 2500 kcal per day (see col 3, lines 35-45),

wherein the weight control benefits of consuming dairy are selected from the group consisting of inducing weight loss, reducing weigh gain, and/or increasing the metabolic consumption of adipose tissue in the individual (see col 2, lines 10-50), and

Howard fails to teach:

wherein the information is distributed by a method selected from the group consisting of verbal communication, pamphlet distribution, print media, audio tapes, magnetic media, digital media, audiovisual media, billboards, advertising, newspapers, magazines, direct mailings, radio, television, electronic mail, electronic media, banner ads, fiber optics, and information on a product package, insert or label or directly accompanying the product. However, the same rejection applied to claim 1 regarding this missing limitation is also applied to claim 22.

As per claim 24, Howard teaches:

A method for promoting *to a potential consumer* the consumption of a calcium-containing-product comprising the public distribution of information describing *obesity-control benefits attained from:*

a) consuming greater than suboptimal amounts of dietary calcium in an amount of at least about 773 mg per day on average during a period of time (see col 5, lines 1-5; col 1, lines 15-20), while

b) maintaining a restricted caloric diet below ad lib in a range of from about 200 kcal to about 2500 kcal per day (see col 3, lines 35-45),

wherein the obesity-control benefits of said product are attributable to the consumption of above suboptimal amounts of calcium in said product for inducing weight loss, reducing weight gain, and/or increasing the metabolic consumption of adipose tissue in the individual (see col 2, lines 5-55), and

Howard fails to teach:

and wherein said distribution of said information is achieved by a method selected from the group consisting of verbal communication, pamphlet distribution, print media, audio tapes, magnetic media, digital media, audiovisual media, billboards, advertising, newspapers, magazines, direct mailings, radio, television, electronic mail, Braille, electronic media, banner ads, fiber optics, laser light shows and information on a product package, insert or label or directly accompanying the product. However, the same rejection applied to claim 1 regarding this missing limitation is also applied to claim 24.

As per claim 2, Howard teaches:

The method of claim 1, wherein the communicating comprises providing information about suboptimal calcium consumption (see col 1, lines 15-20).

As per claim 3, Howard fails to teach:

The method of claim 1, further comprising communicating an effect of calcium consumption on osteoporosis. However, The Milk Mustache campaign teaches the benefit of calcium consumption on osteoporosis (see paragraph 1). Therefore, the same combination applied to claim 1 is also applied to claim 3.

As per claim 5, Howard teaches:

The method of claim 1, wherein the effect on body weight comprises preventing or reducing obesity (see col 2, lines 10-55).

As per claim 6, Howard teaches:

The method of claim 1, wherein the effect on body weight comprises preventing or reducing weight gain (see col 2, lines 10-55).

As per claim 7, Howard teaches:

The method of claim 1, wherein the effect on body weight comprises weight loss (see col 2, lines 10-55).

As per claim 9, Howard teaches:

The method of claim 8, *further comprising communicating the effects of dietary calcium in inducing a metabolic change selected from the group consisting of decreasing intracellular calcium concentrations ([Ca²⁺]_i), stimulating lipolysis, inhibiting lipogenesis, increasing the expression of white adipose tissue uncoupling protein 2 (UCP2), reducing serum insulin levels, thermogenesis, or decreasing the levels of calcitrophic hormones* (see col 2, lines 10-50).

As per claim 10, Howard teaches:

The method of claim 1, wherein the effect on body weight comprises preventing or reducing weight gain and/or adiposity in children (see col 2, lines 10-50). It is inherent that children would have the same benefit obtained by adults.

As per claim 11, Howard teaches:

The method of claim 1, wherein the communication pertains to a class of products to which the calcium-containing product belongs (see abstract).

As per claim 12, Howard teaches:

The method of claim 1, wherein the product is a dairy product (see col 3, lines 35-45).

As per claim 13, Howard teaches:

The method of claim 1, wherein the product is a dietary supplement (see col 14).

As per claim 14, Howard fails to teach:

The method of claim 1, wherein the product is a non-dairy foodstuff naturally high in calcium. However, Official Notice is taken that it is old and well known that certain vegetables such as broccoli are high in calcium and help to fight osteoporosis. It would have been obvious to a person of ordinary skill in the art that vegetable producers would also advertise the benefits of their products for the purpose of selling said products.

As per claim 15, Howard teaches:

The method of claim 1, wherein the product is a foodstuff fortified with calcium (see col 5, lines 1-5).

As per claim 16, Howard teaches:

The method of claim 1, wherein the product is selected from the group consisting of milk, yogurt and cheeses (see col 2, lines 10-55).

As per claim 17, Howard teaches:

The method of claim 1, wherein the product is a liquid supplemented with calcium (see abstract).

As per claim 18, Howard fails to teach:

The method of claim 1, wherein the entity is the manufacturer of the product. However, The Milk Mustache campaign teaches communicating information by a milk processors of California about milk and its benefit to health (see paragraph 5). Therefore, the same combination made in claim 1 is also made in claim 18.

As per claim 19, Howard fails to teach:

The method of claim 1, wherein the entity is a retailer of the product. However, The Milk Mustache campaign teaches communicating information by a milk processors of California about milk and its benefit to health (see paragraph 5). Therefore, the same combination made in claim 1 is also made in claim 19.

As per claim 20, Howard fails to teach:

The method of claim 1, wherein the entity is a trade association whose members sell the product. However, The Milk Mustache campaign teaches communicating information by a milk processors of California about milk and its benefit to health (see paragraph 5). Therefore, the same combination made in claim 1 is also made in claim 20.

As per claim 23, Howard fails to teach:

The method of claim 22 wherein the distributed information recommends at least about 102 *servings* of dairy per month. However, The Milk Mustache campaign teaches communicating information about milk and its benefit to health where the entities that communicate the information are the Milk processors in California (see paragraph 5). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the application was made, to know that any entity having a financial interest in the sale of dairy products or dietary supplements would be motivated to distribute information to potential consumers about milk and its benefits to health, as taught by The "Milk Mustache Campaign" in order to promote the consumption of dairy products by claiming that the consumption of said products would have a benefit against osteoporosis (see The Milk Mustache paragraph 1) and obesity, as taught by Howard. Retailers of calcium-fortified products would be motivated to advertise the benefits of said products such as consuming at least 102 serving of dairy products per month in order to sell more of said products.

As per claim 26, Howard teaches:

The method according to claim 24 wherein said information pertains to a class of products to which said calcium-containing product belongs (see col 2, lines 10-55).

As per claim 27, Howard teaches:

The method according to claim 24, wherein said class of products is dairy products (see col 2, lines 10-55).

As per claim 28, Howard teaches:

The method of claim 1, teaches wherein the communication recommends consuming calcium daily in an amount of at least about 773 mg (see col 5, lines 1-5; col 1, lines 15-20).

As per claim 29, Howard teaches:

The method of claim 1, wherein the communication recommends consuming calcium daily in an amount of at least about 1000 mg (see col 1, lines 15-20).

As per claim 30, Howard teaches:

The method of claim 1, wherein the communication recommends consuming calcium daily in an amount of at least about 1,346 mg (see col 1, lines 15-20).

4. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Howard (US 4,237,118) in view of The Milk Mustache Campaign (agcommcase.ifas.ufl.edu/mustache.html) and further in view of Bruno (US 6,013,622).

As per claim 8, Howard fails to teach:

The method of claim 1, wherein the effect on body weight comprises inducing a metabolic change in an individual. However, Bruno teaches the use of calcium to induce a metabolic change in an individual (see col 12, lines 5-10). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the application was made, to know that any entity having a financial interest in the sale of calcium products or dietary supplements would be motivated to distribute information to potential consumers about the metabolic benefits of said products, as taught by Bruno in order to promote the consumption of calcium products and therefore, sell more of said products.

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5. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Howard (US 4,237,118) in view of The Milk Mustache Campaign (agcommcase.ifas.ufl.edu/mustache.html) and further in view of Christiansen (US 6,159,530).

As per claim 21, Howard fails to teach:

The method of claim 1, but fails to teach wherein the product is identified by a trademark. However, Christiansen teaches a trademark calcium-fortified product (see Christiansen column 9, lines 20-35; "Calcium taste free"). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the application was made, to know that Howard would be motivated to trademark his supplement in order to distinguish his products from others in the market.

Response to Arguments

6. Applicant's arguments filed 11/13/2006 have been fully considered but they are not persuasive. The Applicant argues that the Examiner has not established a *prima facie* case of obviousness and in addition, the Applicant previously submitted evidence showing the present invention's unexpected results, which has led to a significant shift in the scientific community and the food industry. The Applicant further argues that Tabbitta discloses the promotion of milk for its beneficial effects on osteoporosis, not weight-related conditions and the attempt of the dairy industry to market milk as being "cool" not as an agent producing weight-related benefits. Furthermore, the Applicant argues that Tabbitta emphasizes the declining interest in the consumption of milk, attributing it to the perception that milk has a high fat content and this statement,

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according to the Applicant, teaches away from the teaching of the claimed invention, which according to the Applicant involves the use of dietary calcium or dairy, to directly induce weight loss or other weight-related effects. The Examiner answers that Applicant's method claims only recite a single step which is a method of communicating information to potential consumers where said information is communicated by an entity and wherein the communication is by a method selected from the group consisting of verbal communication, tv, radio, etc. That is the reason that Applicant's claims were classified in 705/14 (*i.e.* promotions and advertisements) and not in 514/909 (*i.e.* Drugs or products affecting obesity), where Applicant's patent (US 6,384,087) is classified. Maybe the Applicant evidence of unexpected result has some validity such that consuming 57 servings instead of 45 creates an unexpected result, however, the Examiner would not consider said evidence because the Applicant is not claiming a weight loss product or process but simply a method of distributing information. Furthermore, the information that Applicant is distributing to potential consumers (*i.e.* "consuming dietary calcium in an amount that is above suboptimal and maintaining a restricted caloric diet") is non-functional descriptive material because the content of said information (*i.e.* 123 servings instead of 57 servings) would not have any effect in the distributing step of said information. For example, changing the advertisement distributed to a potential consumer to say 123 servings instead of 57 servings would not slow down an Internet connection and would not make it more difficult to transmit said advertisement via radio or television or other mediums. Therefore, if the Applicant wants that the Examiner considers any evidence of unexpected result, the Applicant has to

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amend the claims to claim a weight loss product. If the Applicant does that, the Examiner would transfer Applicant's claimed invention to art unit 514/909. However, if the Applicant wants to continue claiming the method of distributing information or advertisements to potential consumers via the Internet or radio or other medium, the Examiner wants to mention that there is nothing patentable in said limitations, as it is old and well known in the promotion art to distribute advertisements to potential consumers via the verbal communication, pamphlet distribution, print media, audio tapes, magnetic media, digital media, audiovisual media, billboards, advertising, newspapers, magazines, direct mailings, radio, television, electronic mail, electronic media, banner ads, fiber optics, and information on a product package, insert or label or directly accompanying the product.

Conclusion

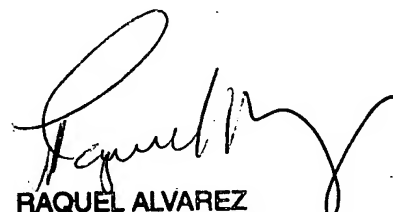
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL LASTRA whose telephone number is 571-272-6720 and fax 571-273-6720. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ERIC W. STAMBER can be reached on 571-272-6724. The official Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Daniel Lastra
January 25, 2007



RAQUEL ALVAREZ
PRIMARY EXAMINER